

REMARKS

Applicants have amended the specification by submitting a substitute specification in order to facilitate the processing of the application under 37 CFR 1.125. Therefore, please find enclosed a Transmittal of Substitute Specification and Statement that Substitute Specification Contains No New Matter. Also enclosed is a marked-up copy of the substitute specification showing the matter being added to and the matter being deleted from the specification.

In the specification, applicants have amended Table B on page 19 in the substitute specification (page 20 as originally filed). Table B is based upon Table D on pages 20 – 21 in the substitute specification (pages 21 – 22 as originally filed). In particular, Table B contains a portion of the nucleic acid sequence of Table D that runs from line 5 through line 12 broken up into repeat copies in this table. Repeats R4 and R5 were mistakenly transposed. The correct order of the repeats can be found in Table D. Table D lists the entire coding sequence for a mini MUC1 gene. The sequence encoding the relevant repeats is highlighted in Appendix A, which represents Table D. These various repeats are set forth in Table B, nucleic acid sequence, and Table C, amino acid sequence. Repeats 4 and 5 in Table C are in the same order as Table D. The longer repeat sequence should be Repeat 5, not Repeat 4. (See Appendix B.) This is clear when all the repeats are aligned. (See Appendix C.) Thus, the error is clerical and, as such, does not introduce new matter. Accordingly, the entry of the amendment is respectfully requested. We are also submitting a corrected disk of the Sequence Listing.

In the specification, applicants have also amended Table C on page 19 in the substitute specification (page 20 as originally filed). The amino acid sequence for Repeat 5 of Table C was mistakenly assigned an incorrect sequence identifier, which was clearly wrong (SEQ ID NO: 1 instead of SEQ ID NO: 21; See Appendix D). The error is clerical, and as such, it does not introduce new matter. Accordingly, the entry of the amendment is respectfully requested.

Applicants have corrected the duplication of a page number in the submission of a substitute specification filed herewith.

In the claims, applicants have amended claims 23, 27, 60, 61, 62 and 64 to replace the word “instances” with the word “copies”. The amendment does not introduce new matter and its entry is respectfully requested.

In the claims, applicants have amended claim 56 to correct a grammatical error. The amendment does not introduce new matter and its entry is respectfully requested.

Turning now to the specific comments by the Examiner.

Claim 23 – 31, 34 – 37, 41 – 42, 45 52, and 54 – 64 were rejected under 35 U.S.C. §112, first paragraph.

The Examiner stated that the claims are not supported by the specification and fail to satisfy the written description requirement.

Applicants respectfully disagree.

Although the terminology in claims 23 and 27 does not appear in the *ipsis verbis* form in the specification as will be shown below they are fully described. Claim 23 will be discussed first.

Claim 23 reads:

A recombinant pox virus comprising a nucleic acid sequence encoding an immunogenic MUC1 fragment comprising 5 to 25 MUC1 tandem repeat units,

The specification explicitly teaches at paragraph [0012] on page 3 (page 4, lines 3-5 of the specification as originally filed):

The recombinant pox virus of the present invention contains a gene encoding immunogenic MUC1 fragment of 5 to 25 tandem repeats of the 20 amino acid unit ...

This is repeated in paragraph [0034] on page 8 (second full paragraph at page 9 of the specification as originally filed). It is taught at paragraph [004] on page 2 (page 2, lines 8-11 of the specification as originally filed), that the tandem repeat unit of MUC1 refers to the 20 amino acid repeated sequence of MUC1 that is described as SEQ ID NO:1.

The claim goes on to read:

the nucleic acid sequence comprising
a first nucleotide sequence encoding the amino acid sequence of SEQ ID NO:1 as
~~one of the tandem repeat units~~ that is SEQ ID NO:2; and

At paragraph [0037] on page 9 (page 10, lines 8-21 of the specification as originally filed), it is taught that one of the nucleotide sequence encoding the amino acid sequence of SEQ ID NO:1 is left unaltered. Specifically:

Preferably, the 60 bp tandem repeat sequence [i.e. the nucleotides encoding the SEQ ID NO:1] can be altered to minimize nucleotide homology without changing the

amino acid sequence. For example, the first tandem repeat in miMUC1 can be left unaltered as follows: [SEQ ID NO:2]

The claim continues:

a second nucleotide sequence encoding ~~[[4]] 2 to 24 copies of the amino acid sequence of SEQ ID NO:1 as the other 4 to 24 tandem repeat units wherein, the second nucleotide sequence comprising [[4]] 2 to 24 instances~~ copies of an altered nucleotide sequence of SEQ ID NO:2 that is altered by changing wobbled nucleotides of the codons of SEQ ID NO:2, ~~the 4 to 24 instances encoding the other 4 to 24 tandem repeat units.~~

It is taught at paragraph [0036] on page 9 (beginning at page 9 of the specification as originally filed) that:

In some preferred embodiments the DNA segment encoding the tandem repeats [which is immediately taught in the paragraph above as being 5 to 25 MUC1 tandem repeats] is altered from the native pattern in such a manner as to reduce duplications of the codons.

The paragraph goes on to teach that by using all the codons encoding the same amino acids one can further reduce the possibility of undesired recombinant invents and that one can also introduce, for example, conservative amino acid changes into different groups of the tandem repeats to further reduce such recombination. Thus, the number 2 to 24 copies of SEQ ID NO:1 is clearly taught to the skilled artisan as the number of copies that remains after one uses one of the 5 to 25 tandem repeat copies having an unaltered nucleotide sequence encoding SEQ ID NO:1. The specification at pages 8 and 9 (at pages 9 and 10 of the specification as originally filed) clearly teaches that one can make alterations in all the remaining copies or other variations. Thus, Applicants respectfully submit that claim 23 particularly as amended fully satisfies the written description requirement. The objection to the language in claim 27 is essentially the same as that in claim 23 and thus, for the reasons described above, is fully supported. Further recitations in claim 27 such as the use of an immunomodulator that is inserted into the pox vector is described at paragraph [0021] on page 5, paragraph [0048] on page 13 and paragraph [0050] on page 13 (page 5, lines 18-20, page 13, lines 25-27 and page 14, lines 1-8 of the specification as originally filed). Claim 63 contains similar limitations. Claims 65-67 are also supported at that spot.

Turning to the Examiner's objection to claim 64, Applicants have the following comments. Pages 8 and 9 (pages 9 and 10 of the specification as originally filed) specifically teach that any number of copies of the MUC1 tandem repeat from 5 to 25 can be used. Thus, it explicitly teaches that 5 can be used, 6 can be used, 7 can be used, 8 can be used, 9 can be used... 23 can be used, 24 can be used, 25

can be used. As explained above, it is taught at paragraph [0037] on page 9 (page 10, lines 8-10 of the specification as originally filed), that preferably while the nucleotide units can be altered the amino acid sequence is not. Thus, teaching that the units in one preferred embodiment are identical tandem amino acid repeat units and it further teaches that one of the nucleic acid tandem repeat units is SEQ ID NO:2 and that the remaining 5 nucleotide sequences can be altered from SEQ ID NO: 2 without changing the amino acid sequence. Thus, Applicants respectfully submit that claim 64 is described.

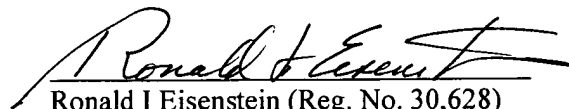
Accordingly, Applicants respectfully submit that the claims satisfy the written description requirement. In view of the fact that there are no other objections to claims, Applicants respectfully submit that all claims are in condition for allowance. Applicants further note that even if the Examiner disagrees with Applicants regarding certain of these claims claims such as newly added claims 65-67 cannot in any way be objected to on this basis. As such, Applicants respectfully submit that all claims are in condition for allowance. Early and favorable action is requested.

In the event that there are any questions relating to this Amendment or to the application in general, it is kindly requested that the Examiner contact the undersigned attorney concerning the same to expedite prosecution of this application.

The Examiner is authorized to charge any fee deficiencies or credit any overpayments associated with this submission to the Nixon Peabody LLP Deposit Account No. 50-0850.

Date: February 23, 2006

Respectfully submitted,



Ronald I Eisenstein (Reg. No. 30,628)
NIXON PEABODY LLP
100 Summer Street
Boston, MA 02110
Tel. (617) 345-6054
Fax (617) 345-1300